K003875

MAR - 1 2001

DePuy
a Johnson & Johnson company

510(k) Summary

NAME OF FIRM:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(K) CONTACT:

Arlene C. Saull, RAC
Sr. Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988

TRADE NAME:

Ti-Replica Hip Stem

COMMON NAME:

Femoral Hip Prosthesis

CLASSIFICATION:

Class II, per 21 CFR, 888.3358

DEVICE PRODUCT CODE:

87 LPH: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented.

SUBSTANTIALLY EQUIVALENT DEVICES:

UNI-ROM Hip Stem	Titanium alloy
Stability Hip Stem	Titanium alloy
Vision AML Hip	Co-Cr-Mo alloy
Titan Hip Stem	Titanium alloy

DEVICE DESCRIPTION:

The Ti-Replica Hip Stem is manufactured from forged titanium alloy. It is a proximally porous coated straight-stem design with a bullet tip, similar to the predicate hip stems, and will incorporate the fluted distal geometry and coronal slot of the UNI-ROM and Stability Hip Stems. It is a collared hip stem similar to the Vision AML Hip Stem. It is designed with a self-locking taper, which is identical to the Titan Hip Stem for use with a DePuy femoral head.

INDICATIONS AND INTENDED USE:

Intended Use:

The subject Ti-Replica Hip Stem is intended for use in total hip arthroplasty and is intended for press-fit (uncemented) use. It can also be cemented with the porous coating providing a means to augment the fixation of the hip stem to the bone cement.

Indications:
Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.

2. Avascular necrosis of the femoral head.

3. Acute traumatic fracture of the femoral head or neck

4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

5. Certain cases of ankylosis.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The subject devices are similar to the predicate hip stem devices, in that they have the same straight stem geometry, indications and intended use, proximal porous coating, sterilization processes and packaging.

Test data demonstrated that the fatigue performance of various features of the subject Ti-Replica Hip Stem is equivalent to the legally marketed predicate AML® and UNI-ROM™ hip stems

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Arlene C. Saull, RAC
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
PO Box 988
Warsaw, Indiana 46581-0988

Re: K003875
Trade Name: Ti Replica® Hip Stem
Regulatory Class: II
Product Codes: LPH and LZO
Dated: December 13, 2000
Received: December 15, 2000

Dear Ms. Saull:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS

510(k) Premarket Notification

510(k) Number (if known) K003875

Device Name Ti-Replica Hip Stem

Indications for Use:

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3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Concurrence of CDRH, Office of Device Evaluation:

Mariana C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003875

Prescription Use ✓ or Over-The-Counter Use ___ (Per 21 CFR 801.109)